DEPARTMENT OF HEALTH AND HUMAN SERVICES

95160d

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

January 6, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 05-11

Jesse W. Koopman, Partner
Anthony Vander Hulst, Partner
West Point Farms, LLC
1449 East 3100 South
Wendell, Idaho 83355

WARNING LETTER

Dear Messrs. Koopman and Vander Hulst:

Our investigator conducted an inspection at your dairy farm located at 1449 East 3100 South, Wendell, Idaho, on November 10, 2004. This inspection confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 342(a)(2)(C)(ii) and (a)(4), and you caused new animal drugs to be unsafe under Section 512(a) of the Act, 21 U.S.C. § 360b(a), and adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii), if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act, 21 U.S.C. § 360b. You sold several dairy cows which had drug residues as follows:

1. On or about April 15, 2004, you sold a culled dairy cow, back tag #[redacted] identified on USDA Case # 03-0865-ID and further identified on USDA-FSIS lab report # 433586, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of Penicillin in the kidney at 0.10 parts per million (ppm). The tolerance for Penicillin in edible tissues of dairy cattle is 0.05 ppm. 21 CFR 556.510. In addition, USDA analysis found Sulfadimethoxine in the liver at 0.44 ppm and 0.26 ppm in the muscle. The tolerance for Sulfadimethoxine in the edible tissue is 0.1 ppm. 21 CFR 556.640.

2. On or about October 5, 2004, you sold a culled dairy cow, back tag #[redacted] identified on USDA Case # 03-0865-ID and further identified on USDA-FSIS lab report # 455556, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from

that animal identified the presence of Penicillin in the kidney tissue at 0.37 ppm, above the 0.05 ppm tolerance. USDA-FSIS also reported finding Sulfadimethoxine in the liver at 13.50 ppm and in the muscle tissue at 11.00 ppm, above the 0.10 ppm tolerance. In addition USDA-FSIS reported finding Sulfamethazine in the liver at 2.74 ppm and 2.62 ppm in the muscle tissue. The tolerance for Sulfamethazine in the edible tissue is 0.1 ppm. 21 CFR 556.670.

A food is adulterated under Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4), "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals, which are ultimately offered for sale for slaughter as food, under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues may enter the food supply. Under Section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii), a food is also adulterated if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act, 21 U.S.C. § 360b.

A new animal drug is adulterated under Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5), if its use does not conform to its approved labeling, thereby making it unsafe within the meaning of Section 512(a)(1)(B) of the Act, 21 U.S.C. § 360b(a)(1)(B). In October 1994, Congress passed the Animal Medicinal Drug Use Clarification Act (AMDUCA), permitting the extra-label use of drugs in animals under certain controlled conditions if the use complies with Sections 512(a)(4) and (a)(5) of the Act, 21 U.S.C. §§ 360b(a)(4) and (a)(5), and the regulations set forth in 21 CFR Part 530. "Extra-label use" means use of a drug in an animal in a manner inconsistent with the approved labeling. Extra-label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in the regulations and the Act.

Our investigation noted the following conditions at your farm:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter;
2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs; and
3. You lack an adequate system for assuring that drugs are used in accordance with their labeling.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where the cow was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act. See 21 U.S.C. § 331(k).

The above is not intended to be an all-inclusive list of violations. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

This letter constitutes official notification under the law and provides you an opportunity to correct. Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Please send your written reply to the Food and Drug Administration, Attention: Lisa Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Ms. Althar at (425) 483-4940.

Sincerely,

Charles M. Breen
District Director

(w/copy of FDA-483):
Dr. Julie Cornett
USDA-FSIS
Technical Service Center
Landmark Center, Suite 300
1299 Farnam Street
Omaha, NE 68102